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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,532	01/25/2002	Jeffrey A. Lyon	003/240/SAP	2344

7590 09/30/2003

ATTN: MCMR-JA (Ms. Elizabeth Arwine-PATENT ATTY)
U. S. Army Medical Research and Materiel Command
504 Scott Street
Fort Detrick, MD 21702-5012

EXAMINER
BASKAR, PADMAVATHI

ART UNIT	PAPER NUMBER
1645	12

DATE MAILED: 09/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/057,532	Applicant(s) LYON ET AL.	
	Examiner Padmavathi v Baskar	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *12* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Claims 1-11 are pending in the application.

Information Disclosure Statement

2. The information disclosure statement (Paper # 12) has been signed and a copy of the same attached with this action.

Specification Informalities.

3. The disclosure is objected for lack of complete information in the specification. For example: on page 6, ATCC address and plasmid pETATpfMSP-1_{42} (3D7) accession number is missing.

Priority

4. This application claims domestic priority under 35, U.S.C. 119 (e) to provisional applications

60/264,535	1/26/01
60/347,564	10/26/01

The examiner has reviewed the applications and priority is accorded as of 1/26/01 to claims 1-11 since the provisional application 60/264,535 discloses a DNA sequence that encodes P.falciparum MSP-1_{42}.

Claim Rejections - 35 USC 112, first paragraph

5. The following is a quotation of the first paragraph of 35 U.S.C. 112

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to

make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to provide an enabling disclosure without complete evidence that the claimed biological materials are known and readily available to the public or complete evidence of the deposit of biological materials.

The specification lacks complete deposit information for the deposit of the ATCC pETATpfMSP-1_{42} (3D7). It is not clear that pETATpfMSP-1_{42} (3D7) is known and publicly available or can be reproducibly isolated from nature without undue experimentation. It is noted that this vector could be used in all claimed methods.

Because one skilled in the art could not be assured of the ability to practice the invention as claimed in the absence of the availability of the vector of the invention, a suitable deposit for patent purposes, evidence of public availability of the pETATpfMSP-1_{42} (3D7) of the invention or evidence of the reproducibility without undue experimentation of the pETATpfMSP-1_{42} (3D7) is required.

If the deposit has been made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository is required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State. Amendment of the specification to recite the date of deposit and the complete name and full street address of

the depository is required. As a possible means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the deposits have not been made under the provisions of the Budapest Treaty, then in order to certify that the deposits comply with the criteria set forth in 37 CFR 1.801-1.809, assurances regarding availability and permanency of deposits are required. Such assurance may be in the form of an affidavit or declaration by applicants or assignees or in the form of a statement by an attorney of record who has the authority and control over the conditions of deposit over his or her signature and registration number averring:

(a) during the pendency of this application, access to the deposits will be afforded to the Commissioner upon request;

(b) all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application;

(c) the deposits will be maintained in a public depository for a period of at least thirty years from the date of deposit or for the enforceable life of the patent of or for a period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longest; and

(d) the deposits will be replaced if they should become nonviable or non-replicable.

In addition, a deposit of biological material that is capable of self-replication either directly or indirectly must be viable at the time of deposit and during the term of deposit. Viability may be tested by the depository. The test must conclude only that the deposited material is capable of reproduction. A viability statement for each deposit of a biological material not made under the Budapest Treaty must be filed in the application and must contain:

1) The name and address of the depository;

2) The name and address of the depositor;

3) The date of deposit;

4) The identity of the deposit and the accession number given by the depository;

5) The date of the viability test;

6) The procedures used to obtain a sample if the test is not done by the depository; and

7) A statement that the deposit is capable of reproduction.

If the deposit was made after the effective filing date of the application for patent in the United States, a verified statement is required from a person in a position to corroborate that the pETATpfMSP-1_{42} ((3D7)) described in the specification as filed is the same as that deposited in the depository. Corroboration may take the form of a showing of a chain of custody from applicant to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the applicant's possession at the time the application was filed.

Applicant's attention is directed to In re Lundack, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 CFR 1.801-1.809 for further information concerning deposit practice.

NOTE THE CURRENT ATCC DEPOSITORY ADDRESS

American Type Culture Collection, 10801 University Boulevard, Manassas, VA 20110-2209

Applicant is reminded to amend the specification accordingly.

Claim Objections

7. With regard to claim 3, the abbreviation "MSP -1_{42}" is used without definition upon its first appearance in the claims.

8. Claim 3 recites a method for inducing an immune response against malaria infection and Claim 5 recites a method for inducing a protective immune response to malaria. However, in the art of infectious disease it is common and routine to use protective immune response

against (malaria) infection and immune response to (malaria) antigen because one would like to induce a protective immune response against an infection. Similarly an immune response to a given antigen is used to make antibodies or T-cell response etc.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a), which forms the basis for all obviousness rejections, set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the
> (b) invention was made.

10. The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kumar et al 1995, Molecular Medicine 1, 325-332 or Chang et al 1996, Infection and Immunity 64: 253-261 in view of Genton et al 2000, vaccine 18: 2504-2511.

The claims are directed to a vaccine composition comprising P. falciparum MSP-1_{42} and an adjuvant selected from the group consisting of A, B, C, D and E, wherein said *P. falciparum*

is 3D7 (claims 1-2). Claims are also drawn to method for inducing an immune response against malaria infection (claims 3-4) and a method of inducing protective immune response to malaria (claims 5-11) comprising administering a composition comprising. falciparum MSP-1_{42} and an adjuvant selected from the group consisting of A, B, C, D and E.

Kumar et al teach a vaccine composition comprising recombinant MSP-1_{42} from *P.falciparum*, FVO strain and Freund's adjuvant (see abstract). Kumar et al also teach a method of inducing an immune response to recombinant MSP- 1_{42} in Aotus monkeys by injecting recombinant protein in Freund's adjuvant (see page 327 lower right column). To determine whether the immunization with said protein induced an antibody response, sera from immunized animals were incubated with parasites (see page 328, lower left column and Table 1) in neutralization assays and inhibition of erythrocyte invasion was counted. Further, the prior art teaches a method for inducing protective immunity against malaria infection in Aotus Monkeys (see page 327, right column last paragraph) by injecting recombinant protein in adjuvant at multiple times. The immunized monkeys were challenged with *Plasmodium* parasites (page 328, upper left column). Immunized and control monkeys blood was collected and protective immunity was measured by estimating the percent parasitaemia (counting the parasites) in the blood.

Chang et al teach a vaccine composition comprising a recombinant baculovirus 42kD protein i.e., MSP-1_{42} (see abstract and page 254, left column, first paragraph under Materials and Methods) from *P.falciparum,* FUP strain and complete Freunds adjuvant. Further, to determine whether the immunization with said protein induced an immune response, sera from immunized monkeys were incubated with parasites (see page 254 Materials and Methods and Figure 1 and Table 2) in neutralization assays and inhibition of erythrocyte invasion was counted indicating that immunization with vaccine composition induced effective antibody

response. Further, monkeys immunized with vaccine composition were protected against challenge infection. However, Kumar et al or Chang et al do not teach adjuvant selected from the group consisting of A, B, C, D and E and MSP-1_{42} is from P.falciparum 3D7.

Genton et al teach three component blood stage malaria vaccine including MSP 1 and MSP2 from *P.falciparum* 3D7 and an adjuvant ISA720 containing oil squalene, emulsifier from the mannide mono-oleate family, i.e., adjuvant B. This adjuvant has been shown to be safe and is used for human studies (see page 2505 under Materials and Methods) Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to use protein from various strains including P.falciparum strain 3D7 (selecting a vaccine strain depends on the endemic area of the region) and adjuvant B in a vaccine composition, in a method of inducing an immune response or in a method of inducing protective immune response against malaria infection with a reasonable expectation of success because it would help in preparing a safe vaccine for human immunization for combating fatal malaria infection caused by *P.falciparum*. An artisan of ordinary skills would have been motivated to prepare MSP-1_{42} as taught by Kumar or Chang from Plasmodium 3D7 and combine with an adjuvant B as taught by Genton et al to a vaccine composition and use such composition in a method of inducing an immune response or a method of inducing a protective immune response because the prior art suggests that the *P.falciparum* 3D7 is an effective vaccine candidate and adjuvant B is safe for human use (Genton et al) and Kumar et al or Chang et al teach recombinant MSP-1_{42} induces an effective immune response in Monkeys and protects monkeys against challenge infection. The claimed invention is a prima facie obvious over Kumar et al or Chang et al, each in view of Genton et al absent any convincing evidence to the contrary.

Status of Claims

13. No claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4 PM EST

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Padma Baskar Ph.D.

9/16/03

LYNETTE R. F. SMITH
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